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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,542	10/24/2003	Niklas Axen	1510-1070	6890
466	7590	06/30/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			XU, LING X	
			ART UNIT	PAPER NUMBER
			1775	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,542

Applicant(s)

AXEN ET AL.

Examiner

Ling X. Xu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/29/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 22-27 in the reply filed on 5/11/2005 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities:

On page 3, line 1, the section title should be --Summary of the Invention--. The letter "o" in "of", the letter "e" in "the", and the letter "o" in "Invention" were missing.

On page 15, line 26, "my" between "reduced" and "ball" should be --by--.

Appropriate correction is required. The examples listed above are not conclusive.

Applicant should review the entire specification carefully for similar editorial errors.

Claim Objections

3. Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 27 recites that "the outer layer comprising a bioactive or biocompatible material", which is a broad recitation, and the claim also recites "preferably calcium phosphate, apatite, calcium carbonate or calcium fluoride", which is the narrower statement of the range/limitation.

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The following examination will be based on the broad recitation that the outer layer comprising a bioactive or biocompatible.

The broad recitation of claim 27 does not further limit the subject matter of claim 24 because claim 24 already recites that the outer layer should include material having ions of carbonates, phosphates or fluorides, which is narrower than the broad limitation recited in claim 27. It is suggested that, in order to further limit the previous claim, the broad recitation should be removed from the claim.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 22-27 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 22-27 of copending Application No. 10/691,499. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-38 of copending Application No. 10/377,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31-38 of the copending application recites the same surface coated device comprising a substrate and a surface coating that comprising one powder mixture or several powder mixtures having different chemical composition as claimed in the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 22 and 27 recite that the binding layer comprising hydrated calcium aluminate particles of less than 2 um and the bulk layer comprising hydrated calcium aluminate having a grain size between 3 and 30 um.

The specification describes the powder grain size is preferably below 10um and more preferably between 0.1 and 3um on page 10, lines 4-5 and the grain size (of calcium aluminate powder) was reduced by ball milling to less than 10um on page 15, lines 26. However, the specification does not describe how to make and use the binding layer having hydrated calcium hydrated calcium aluminate particles of less than 2um, the bulk layer comprising hydrated calcium aluminate having a grain size between 3 and 30 um. The recitations were not sufficiently described in the specification to enable one skilled in the art to make and/or use the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22, line 3, it recites that the binding layer is in contact with the substrate. There is insufficient antecedent basis for the limitation of "the substrate" in the claim.

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It should be noted that the claimed subject matter in claim 22 is directed to a coating. The substrate as recited does not provide a patentable distinction on the structure of the claimed coating because the coating does not include the substrate.

It should also be noted that claim 22 (also in claim 27) recites that “the outer layer comprising a bioactive or biocompatible material”, which is a broad recitation, and the claim also recites “preferably calcium phosphate, apatite, calcium carbonate or calcium fluoride”, which is the narrower statement of the range/limitation. The claim will be interpreted based on the broad recitation that the outer layer comprising a bioactive or biocompatible. If applicant wishes that the Examiner to consider the scope of the narrower limitation, the narrower limitation should be removed from the claim and presented in a dependent claim.

In claim 24, line 10, it is unclear if the “a substrate” is the same as the substrate recited in line 2 of the claim. It is suggested that “a substrate” be changed to -- the substrate--.

In claim 24, line 12, it recites that one of the non-hydrated powder mixtures may be applied on the substrate. It is unclear if it is only one coating layer on the substrate when only one mixture is applied on the substrate or the coating layer with the same “one mixture” is applied on top of each other on the substrate.

In claim 25, line 4, it is unclear if the “another biocompatible metal” is referred to any biocompatible metal except the alloys listed.

In claim 26, it is unclear if “medical device” includes medical device for implantation, artificial orthopedic device, spinal implant, joint implant, attachment element, bone nail, bone screw, or a bone reinforcement plate. It is also unclear if the “medical device for implantation” includes artificial orthopedic device, spinal implant, attachment element, bone nail, bone screw,

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or a bone reinforcement plate. The scope of the claim is not clear since some of the listed devices/implants overlap with other listed devices/implants. It is also unclear what the “attachment element” is referred to .

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Arima et al (US 5,480,438).

Arima discloses a metallic implant base, such as Ti (Example 1), coated with two bioactive ceramic layers. An inner bioactive ceramic layer is coated on the implant base. The inner bioactive layer is vitrified to improve the bonding of the inner bioactive layer to the metallic implant base. An outer bioactive ceramic layer is coated on the inner bioactive ceramic layer (abstract).

Arima also discloses that the outer layer and inner layer may comprise a mixture of hydroxyapatite and calcium phosphate. The inner layer may also comprise a ceramic such as biodegradable glass (col. 3, lines 35-50). The inner layer is considered to be the ceramic powder binder phase layer.

It is noted that claim 24 is a product-by-process claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (MPEP

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2113). “[E]ven though product – by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966.

As stated above, in claim 24, line 12, it recites that one of the non-hydrated powder mixtures may be applied on the substrate. It is unclear if it is only one coating layer on the substrate when only one mixture is applied on the substrate or the coating layer with the same “one mixture” is applied on top of each other on the substrate.

If claim 24 is interpreted as only one coating layer on the substrate, Arima meets all the limitations of claims 24-26.

If claim 24 is interpreted as applying one of said non-hydrated powder mixture on top of each other on the substrate. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al (US 5,480,438) as set forth below.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arima et al (US 5,480,438) in view of the same reference.

Arima discloses a metallic implant base, such as Ti (Example 1), coated with two bioactive ceramic layers. An inner bioactive ceramic layer is coated on the implant base. The inner bioactive layer is vitrified to improve the bonding of the inner bioactive layer to the metallic implant base. An outer bioactive ceramic layer is coated on the inner bioactive ceramic layer (abstract).

Arima also discloses that the outer layer and inner layer may comprise a mixture of hydroxyapatite and calcium phosphate. The inner layer may also comprise a ceramic such as biodegradable glass (col. 3, lines 35-50). The inner layer is considered to be the ceramic powder binder phase layer.

It is noted that claim 24 is a product-by-process claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (MPEP 2113). “[E]ven though product – by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966.

If claim 24 is interpreted as applying one of said non-hydrated powder mixture on top of each other on the substrate. Arima does not disclose the inner layer comprising multilayer structure. However, the additional layer(s) applied on tope of each other on the substrate is simply the duplicates of the structure of the inner layer disclosed by Arima.

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It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. V. Bemis Co.*, 193 USPQ 8. The court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced, *see* MPEP 2144.04 VI B.

Therefore, absent of showing unexpected results, it would have been obvious to one of ordinary skill to apply additional layers to the Arima's surface coated device by simply duplicating the same structure of the inner layer disclosed by Arima in order to make a more efficient surface coated device

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling X. Xu whose telephone number is 571-272-1546. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah D. Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ling X. Xu
Examiner
Art Unit 1775

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